K032640

SEP 11 2003

2.3 510(k) Summary

510(k) Summary for Traditional 510(k)
U-Systems Ultrasound System
U-Systems Inc.

Prepared August 15, 2003

Product Name:	FFBU Diagnostic Ultrasound System
Manufacturer:	U-Systems Inc. 110 Rose Orchard Way San Jose, CA 95134 Telephone (408) 750-1323 Fax (408) 571-8979
Generic Name	Diagnostic Ultrasound System
Classification Name:	Ultrasound Imaging System and Transducers (Class II); Classification codes: IYO 892.1560 System, Imaging Pulsed Echo, Ultrasonic ITX 892.1570 Transducer, Ultrasonic, Diagnostic
Contact Person:	Sheila W. Pickering Ph.D. 2081 Longden Circle Los Altos, California 94024 Telephone/Fax 650 969 6114 e-mail: swpraqa@aol.com

A. Legally Marketed Predicate Device
The FFBU System modification is substantially equivalent to the original USI-2000 Horizon device cleared in 510(k) (K022517). The intended use and the technological characteristics of the modification are the same as the predicate device.

B. Device Description
The FFBU Diagnostic Ultrasound system represents hardware and software changes to the predicate device and changes it to a Track 3 system.

C. Intended Use
The device is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of a patient's breast when used with an automatic scanning linear array transducer.

D. Substantial Equivalence
The FFBU System is substantially equivalent to the to the USI-2000 Horizon System. with regard to intended use and technological characteristics.

E. Performance Data
The FFBU System performance has been verified according to the FFBU System Test Plan. The FFBU Test Plan and the summary of test results to date are included in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2003

U-Systems, Inc.
% Mr. Heinz-Joerg Steneberg
Responsible Third Party Official
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K032640
Trade Name: U-Systems FFBU Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYO and ITX
Dated: August 25, 2003
Received: August 27, 2003

Dear Mr. Steneberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the U-Systems FFBU Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

L9-5 XW MHz

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device

can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

3.2. Diagnostic Ultrasound Indications for Use Forms (No New Indications for Use; Previously Cleared Indications for Use)

Diagnostic Ultrasound Indications for Use

510(k) Number(s):

Device Name: U-Systems FFBU Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)*	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		N								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Laproscopic										
Peripheral Vascular										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										

U-Systems FFBU Diagnostic Ultrasound System is intended for diagnostic breast examinations.

N = new indication
P = previously cleared by FDA

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032640

Prescription Use ✓

Diagnostic Ultrasound Indications for Use

510(k) Number:

Device Name: L 9-5 XW MHz Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)*	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		N								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Laproscopic										
Peripheral Vascular										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										

U-Systems L 9-5 XW MHz Transducer is intended for diagnostic breast examinations.

N = new indication
P = previously cleared by FDA

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032640

Prescription Use ✓